Remarks

Reconsideration of this application is respectfully requested.

I. Claim Amendments

Upon entry of the foregoing amendment, claims 1-10, 15, 16, 22-27, 29, 32-34 and 36-39, 41 and 44-49 are pending in the application, with claim 1 being the sole independent claim. Claims 15, 16, 22-27, 32, and 44-45 are sought to be amended. Claims 28 and 31 are sought to be canceled. No new matter is added by way of these amendments. It is respectfully requested that the amendments be considered and entered.

Support for the amendment of claims 15 and 16 can be found, *inter alia*, throughout the specification, *e.g.*, page 8, lines 4-7; page 15, lines 29-31; page 18, lines 12-15; page 23, lines 5-9; and original claim 11.

II. Telephonic Interview

Applicants are grateful for the courtesy extended by Examiner Walter Schlapkohl in a telephonic interview on January 9, 2007. The 1994 Sigma Catalog reference has been cited during prosecution of the present application. Applicants' representative, Doug Golightly, a patent agent employee of the assignee (Invitrogen Corporation) of the present application, requested copies of additional pages from the 1994 Sigma Catalog reference. The Examiner agreed to try and obtain the requested pages and forward them to Applicants. Subsequently, Applicants received the requested pages from the Examiner. Applicants thank the Examiner for his assistance.

III. Personal Interview

Applicants gratefully acknowledge the courtesies extended by Examiners Walter Schlapkohl and David Guzo during a personal interview held April 18, 2007, with Applicants' representative, Doug Golightly.

The claims currently rejected under 35 U.S.C. §§ 102(b) and 112, first and second paragraphs, were discussed. In particular, the disclosure of the 1994 Sigma Catalog, was discussed with regards to the rejection under 35 U.S.C. § 102(b). No agreement was reached.

IV. Claim Rejections Under 35 U.S.C. § 112, first paragraph

Claims 1-10, 15-16, 22-29, 31-34, 36-39, 41 and 44-49 were "rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement." (Office Action, page 2.) Applicants respectfully disagree.

The test for the written description requirement is whether one skilled in the art can reasonably conclude that the inventor has possession of the claimed invention in the specification as filed. (*See,* Manual of Patent Examining Procedure (MPEP) § 2163(I) at 2100-165 (eighth edition, October 2006) and *VasCath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991).)

The Examiner appears to focus this rejection on the claim elements "buffer salts" and "solvent". For example the Examiner states,

> [t]he examples in the specification are neither representative nor predictive of any other solvents used in combination with any set of buffer salts such that dry culture medium can be produced which supports the cultivation and/or growth and/or differentiation of any eukaryotic cell.

(Office Action, page 4.) Applicants respectfully disagree.

With regards to "pH-opposing forms of buffer salts", the specification provides, *inter alia*, chemical and functional characteristics to provide sufficient distinguishing and/or identifying characteristics of pH-opposing forms of buffer salts for producing a eukaryotic dry powder culture medium. For example, the 09/705,940 (the '940) application recites that, "pH-opposing forms of components are conjugate acid-base pairs in which the members of the pair can either raise the pH or lower it to achieve the desired pH of the solution." (the '940 application, page 23, lines 29-31.) Additionally, Applicants assert that one skilled in the art at the time of the invention, upon review of the '940 application, would readily identify pH-opposing forms of buffer salts that could be used in accordance with the subject matter of the present claims, *e.g.*, to produce an automatically pH-adjusting eukaryotic dry powder culture medium.

During the personal interview on April 18, 2007 with Applicants' representative, Examiner Schlapkohl expressed concern related to producing an <u>automatically pH-adjusting</u> eukaryotic dry powder culture medium having the desired final pH upon reconstitution using <u>any</u> pH-opposing forms of buffer salts and using <u>any</u> solvent comprising water for reconstitution. Applicants address these concerns below.

With regards to obtaining a eukaryotic dry powder culture medium having the desired final pH upon reconstitution, Example 17 of the '940 application provides an example of a method for determining the ratio of pH-opposing forms of buffer salts required to be added to a eukaryotic dry powder culture medium to automatically provide a desired final pH upon reconstitution with a solvent. This particular procedure takes into account the composition of the solvent used for reconstitution. For instance, Example 17 describes determining the ratio of pH-opposing forms of buffer salts by reconstituting a dry powder medium (DPM) with a solvent and then adding pH-opposing forms of buffer salts to arrive at the desired pH. Subsequently, the determined ratio of pH-opposing forms of buffer salts is incorporated into the DPM. Therefore, the presence of any additional components in the solvent is taken into account when the ratio of pH-opposing forms of buffer salts is determined. For example, if the solvent for reconstitution comprises both water and an inorganic solvent, the ratio of pH-opposing forms of buffer salts would be determined in the presence of the solvent comprising both water and the inorganic solvent.

In summary, the '940 application describes every element of the claims in sufficient detail that one skilled in the art, upon reading the present application as filed, would reasonably conclude that the inventors had possession of the claimed invention.

In view of the above, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 1-10, 15-16, 22-29, 31-34, 36-39, 41 and 44-49 under 35 U.S.C. § 112, first paragraph.

V. Claim Rejections Under 35 U.S.C. § 112, second paragraph

Claims 15-16, 22-27, 41 and 44-45 were "rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention." (Office Action, page 5.)

A. Claims 15, 16 and 41

Claims 15 was rejected as being "vague and indefinite in that the metes and bounds of 'conditions favoring growth or differentiation of the eukaryotic cell' are unclear". (Office Action, page 6.) Applicants believe claims 16 and 41 are rejected for a similar reason. Applicants respectfully disagree with this rejection of claims 15, 16 and 41.

Solely to advance prosecution, and not in acquiescence to the Examiner's rejection, claims 15 and 16 have been amended to delete the reference to differentiation and replace the term "favoring" with "supporting". Applicants assert that conditions supporting the growth of a eukaryotic cell are well known in the art. Therefore, the metes and bounds of claim 15, 16 and 41, as amended herein, are clear.

In view of the above, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 15, 16 and 41 under 35 U.S.C. § 112, second paragraph.

B. Claims 22-27 and 44-45

Claims 22-27 and 44-45 "are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention." (Office Action, page 5.) Applicants respectfully disagree.

However, solely to advance prosecution, and not in acquiescence to the Examiner's rejection, claims 22-47 and 44-45 have been amended to delete the phrase "or a cell derived therefrom".

In view of the above, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 22-27 and 44-45 under 35 U.S.C. § 112, second paragraph.

VI. Claim Rejections Under 35 U.S.C. § 102(b)

Claims 1-2, 5-8, 10, 15-16, 22-29, 31-34, 36-39, 41 and 44-45 were "rejected under 35 U.S.C. 102(b) as being anticipated by SIGMA catalog 1994" (henceforth SIGMA). (Office Action, page 8.) Applicants respectfully disagree.

An anticipation rejection under 35 U.S.C. § 102 requires a showing that each limitation of a claim is found in a single reference, practice, or device. (*See In re Donohue*, 766 F.2d 531, 534 (Fed. Cir. 1985).)

In the present Office Action the "Examiner invites Applicant to show where in the SIGMA reference it is taught that the addition of sodium bicarbonate is added to something other than the dry powder medium and where in the SIGMA reference it is taught that the dry powder media does not result in a desired pH upon reconstitution of the powder." (Office Action, page 9.)

In response, Applicants point the Examiner to pages 201-203 of SIGMA, which shows both of the these features. With regards to the addition of sodium bicarbonate being added to

something other than the dry powder medium, Applicants refer the Examiner to pages 201 and 203 which both show a procedure wherein the powdered medium is dissolved in a solvent. Afterwards, sodium bicarbonate is added to the solution. Additionally, the sodium bicarbonate addition tables on pages 201-202 and 203 refer to using a 7.5% sodium bicarbonate solution. Therefore, the sodium bicarbonate is not part of the dry powder medium.

With regards to having the desired final pH upon reconstitution, the addition of sodium bicarbonate to the reconstituted medium, as discussed in SIGMA, changes the pH of the reconstituted medium. Hence, the dry powder culture medium in SIGMA, referred to by the Examiner, does not have a desired final pH upon reconstitution. Additionally, pages 201 and 205, second column of text, refer to adjusting the pH of the reconstituted medium.

As shown above, the sections of the SIGMA reference cited by the Examiner do not disclose an automatically pH-adjusting eukaryotic dry powder culture medium having the desired final pH upon reconstitution and wherein the dry powder culture medium comprises sodium bicarbonate. Consequently, the cited sections of the SIGMA reference do not anticipate the claims as presented herein.

In view of the above, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of the claims under 35 U.S.C. § 102(b).

VII. Claim Rejections Under 35 U.S.C. § 103

Claims 1-10, 15-16, 22-29, 31-34, 36-39, 41 and 44-45 were "rejected under 35 U.S.C. 103(a) as being unpatentable over SIGMA Catalog 1994 (of record) in view of Fike et al (WO 98/36051; of record)." (Office Action, page 10.) Applicants respectfully disagree.

To establish a *prima facie* case of obviousness, the Examiner must, *inter alia*, show that the references upon which she or he relied teach every limitation of the currently claimed invention. (*In re Royka*, 490 F.2d 981, 985 (Fed. Cir. 1974).)

The Examiner states "the construction of the various media set forth in SIGMA involve the determination of a ratio between monobasic and dibasic phosphate salts which give a desired final pH upon reconstitution of the powder." (Office Action, page 16.) Applicants respectfully disagree.

As discussed above, SIGMA does not disclose a eukaryotic dry powder culture medium having the desired final pH upon reconstitution. Therefore, SIGMA does not teach, *inter alia*,

determining the ratio of pH-opposing forms of buffer salts required to be added to a eukaryotic dry powder culture medium to automatically provide a desired final pH upon reconstitution of the dry powder culture medium with a solvent comprising water. In addition, the Examiner concedes Fike *et al.* does not disclose the use of pH-opposing forms of buffer salts in dry powder media.[1] Therefore, Fike *et al.* does not cure the deficiencies of SIGMA. Since SIGMA and Fike *et al.* do not teach every limitation of the currently claimed invention, a *prima facie* case of obviousness has not been established.

In view of the above, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of the claims under 35 U.S.C. § 103(a).

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[1] The Examiner has noted that "Fike does not specifically teach using pH-opposing forms of buffer salts to maintain the pH of the medium at a desired level". (Office Action, July 26, 2004, page 6.)

Conclusion

It is not believed that extensions of time are required beyond those that may otherwise be provided for in accompanying documents. However, if additional extensions of time are necessary to prevent abandonment of this application, The United States Patent and Trademark Office is hereby authorized to charge any fee deficiency required to prevent abandonment of the current application or credit any overpayment to Deposit Account 503994.

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. Applicants believe that a full and complete Reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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